UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

Case No. 1:22-cv-441

Hon. Hala Y. Jarbou

ABBOTT LABORATORIES, a corporation doing business as ABBOTT NUTRITION, and KEENAN S. GALE, TJ HATHAWAY, and LORI J. RANDALL, individuals,

Defendants.
_____/

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned counsel and on behalf of the United States Food and Drug Administration ("FDA"), having filed a Complaint for Permanent Injunction ("Complaint") against Abbott Laboratories, a corporation doing business as Abbott Nutrition, and Keenan S. Gale, TJ Hathaway, and Lori J. Randall, individuals, (collectively, "Defendants"), and Defendants having appeared and having consented to the entry of this Consent Decree of Permanent Injunction (the "Decree") without contest and before any testimony has been taken, and the United States of America having consented to this Decree,

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter and over all parties to this action under 28 U.S.C. §§ 1331 and 1345, 21 U.S.C. § 332, and its inherent equitable authority.

2. The Complaint states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq*. ("Act").

3. The Complaint alleges that Defendants violate 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into

interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4).

4. The Complaint alleges that Defendants violate 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce articles of food, namely infant formula as defined in 21 U.S.C. § 321(z), that are adulterated within the meaning of 21 U.S.C. § 350a(a)(3), 21 U.S.C. § 350a(b)(2), and 21 C.F.R. Part 106.

5. The Complaint alleges that Defendants violate 21 U.S.C. § 331(k) by causing articles of food that are held for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4).

6. The Complaint alleges that Defendants violate 21 U.S.C. § 331(k) by causing articles of food, namely infant formula as defined in 21 U.S.C. § 321(z), that are held for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 350a(a)(3).

7. For purposes of this Decree, the following definitions shall apply:

A. "Associated Persons" shall refer collectively to each and all of Defendants' officers, agents, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them (including individuals, partnerships, corporations, subsidiaries, and "doing business as" entities) who are involved with the manufacture, processing, preparing, packing, labeling, holding, or distribution of articles of food covered by paragraph 7(F) or paragraph 7(G) at or from the Sturgis Facility;

B. "CGMP Regulations for Human Food" shall refer to the current good manufacturing practice requirements in Subpart B of 21 C.F.R. Part 117 (Current Good

Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food);

C. "Days" shall refer to business days;

D. "Infant Formula CGMP Regulations" shall refer to the current good manufacturing practice requirements in Subpart B of 21 C.F.R. Part 106 (Infant Formula Requirements Pertaining to Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Records and Reports, and Notifications);

E. "Inventory Products" shall refer only to the non-recalled powdered finished products manufactured at the Sturgis Facility and in Defendants' possession, custody, or control as of March 18, 2022, the close of FDA's inspection at Defendants' facilities located at 901 North Centerville Road, Sturgis, Michigan 49091;

F. "Other Operations" shall refer to Defendants' manufacture, processing, preparing, packing, labeling, holding, and/or distribution at or from the Sturgis Facility of any infant formula, as that term is defined in 21 U.S.C. § 321(z), in powdered form, except for Inventory Products defined in paragraph 7(E) and products subject to Specialty Operations described in paragraph 7(G);

G. "Specialty Operations" shall refer to Defendants' manufacture, processing, preparing, packing, labeling, holding, and/or distribution at or from the Sturgis Facility of any article of food that is:

(1) Any powdered infant formula covered by 21 U.S.C. § 350a(h)(1); or

(2) Any powdered product for non-infants (older than 12 months of age) that serves similar nutritional purposes as any formulation of powdered infant formula covered by 21 U.S.C. § 350a(h)(1); and

H. "Sturgis Facility" shall refer to the facilities located at 901 North Centerville Road, Sturgis, Michigan 49091.

Specialty Operations

8. Subject to paragraph 11(A), upon entry of this Decree, Defendants and each and all of their Associated Persons who have received actual notice of this Decree are permanently restrained and enjoined under 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, from conducting Specialty Operations, unless all the following conditions are met:

A. Defendants, at their expense, shall retain or continue retention of an independent person or persons ("Expert") who is without any personal or financial ties (other than a retention agreement or agreements to satisfy the requirements of this Decree and/or to perform other consulting or testing work for Abbott Nutrition) to Defendants or their families, and who, by reason of training, education, and experience, is qualified to:

(1) Evaluate the facilities, methods, processes, and controls at the Sturgis Facility to ensure that Defendants' products are manufactured, processed, prepared, packed, labeled, held, and distributed in compliance with this Decree, the Act, the CGMP Regulations for Human Food, and the Infant Formula CGMP Regulations; and

(2) Inspect the Sturgis Facility to determine whether Defendants' facilities, methods, processes, and controls are continuously operated and administered in conformity with this Decree, the Act, and its implementing regulations;

B. Defendants shall notify FDA in writing of the identity and qualifications of the Expert within two days after retaining the Expert, and, in coordination with the Expert, Defendants shall:

(1) Verify the dry-out procedures (including time and temperature controls) for production equipment and processing environments, and validate the test method for moisture verification used to assess dryness after the dry-out procedures for production equipment and processing environments. Where applicable, Defendants may rely on completed action described in Defendants' response(s) to the FDA Form-483 issued on March 18, 2022 ("Form-483 Response");

(2) Conduct pre-production cleaning, sanitizing, and dry-out of production equipment and processing environments (using the verified dry-out procedures and the validated test method), followed by environmental testing for pathogens in the processing environment. Where applicable, Defendants may rely on completed actions already conducted in coordination with the Expert or as described in Defendants' Form-483 Response; and

(3) Prior to initiating production pursuant to paragraph 8, provide FDA with the Expert's report documenting completion of the verification and validation activities and pre-production review set out in paragraph 8(B);

C. If Defendants choose to restrict Specialty Operations to specified equipment and processing environments, then Defendants shall ensure that any cleaning, sanitizing, dry-out, and/or environmental testing during the pendency of Specialty Operations of equipment and processing environments that are not part of Specialty Operations is accomplished in a manner that protects against contamination of the specified equipment and processing environments (and utensils therein) that are part of Specialty Operations;

D. Defendants shall, as and when feasible, prioritize production in a manner that minimizes the risk of market disruption;

E. Prior to distribution of each product lot produced during Specialty Operations, Defendants shall ensure that a qualified individual in Defendants' quality unit reviews the batch record, the test results for in-process and finished product, and the environmental monitoring results that pertain to the product lot, and certifies in writing to FDA that such lot meets all specifications;

F. Defendants shall ensure that environmental monitoring during Specialty Operations consists of routine sampling and, when appropriate, investigative sampling, and that a qualified individual in Defendants' quality unit conducts trending analyses of environmental monitoring results from both routine and investigative sampling;

G. Defendants shall collect in-process and finished product samples during Specialty Operations and shall analyze the powdered infant formula samples for *Cronobacter* spp. and *Salmonella* spp., in the manner specified in 21 C.F.R. § 106.55, and shall analyze the powdered non-infant product samples for *Salmonella* spp. If any test of in-process or finished product detects the presence of *Cronobacter* spp. and/or *Salmonella* spp., Defendants shall:

(1) Cease production at the earliest time practicable and, in any event, no later than the completion of any batch then in progress, dispose of the affected in-process and/or finished product batch, conduct a thorough contamination-source determination (i.e., root-cause analysis), and adequately remediate the processing equipment and environment. Defendants shall maintain records of all the steps taken pursuant to this paragraph and shall make the records available to FDA immediately upon request. After a cessation of production pursuant to this paragraph, Defendants shall not resume production unless and until they receive

written notice from FDA that Defendants may resume production. Within fifteen days after receipt of Defendants' written request to resume production, unless FDA determines that, based on the complexity of the issues, a longer time frame is necessary, in which case FDA can give Defendants notice that FDA needs an additional fifteen days to complete its review, FDA will review Defendants' request to resume production and provide written notification to Defendants either permitting resumption or explaining the basis for FDA's decision not to permit resumption of production, including the concerns with Defendants' submission. After addressing all concerns described in FDA's written notification of a decision not to permit resumption, Defendants may submit a new request to resume production, and the process described in paragraph 8(G)(1) shall be repeated until Defendants receive written notification from FDA that they may resume production. In no circumstance shall FDA's silence be construed as a substitute for written notification;

(2) Forward the test results detecting the presence of *Cronobacter* spp. and/or *Salmonella* spp. in in-process and/or finished product to FDA within twenty-four hours after receipt by Defendants (along with a written statement confirming that Defendants have ceased production in accordance with paragraph 8(G)(1)), speciate each *Cronobacter* spp. isolate to determine whether it is *Cronobacter sakazakii*, and forward each *Cronobacter sakazakii*-positive test result to FDA within twenty-four hours of receipt by Defendants; and

(3) Retain each *Cronobacter sakazakii* and *Salmonella* spp. isolate under appropriate storage conditions for three years from the date of the test result detecting the presence of *Cronobacter sakazakii* and/or *Salmonella* spp. in that isolate, and each isolate is to be provided to FDA within five days of receipt of a written request;

H. Defendants shall maintain a record of all sales and distribution of products, including shipping documents and the following information for the product distributed: the product name; the product size and configuration if variations exist; the batch, lot, and manufacturing codes; and the names of customers to whom the product is shipped, along with quantities shipped to each such customer. Defendants shall make the records described in this paragraph available to FDA immediately upon request; and

I. Defendants shall, in accordance with the procedures in paragraph 10, destroy all Inventory Products defined in paragraph 7(E) that have not been distributed within fifteen days after Defendants initiate production under Specialty Operations. The parties may mutually agree in writing to modify this fifteen-day time frame, which modification may be granted without seeking leave of Court. To the extent that Defendants are under a separate legal obligation to preserve all or a portion of the Inventory Products, Defendants shall be permitted to segregate and retain such Inventory Products for the duration of such preservation obligation.

Other Operations

9. Upon entry of this Decree, Defendants and each and all of their Associated Persons who have received actual notice of this Decree are permanently restrained and enjoined under 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, from conducting Other Operations, unless all the following conditions are met:

A. Defendants shall have continuously complied with paragraph 8 since entry of this Decree;

B. Defendants shall ensure that the Sturgis Facility and equipment therein: (1) are cleaned and sanitized to render them suitable for manufacturing, processing, preparing, packing, labeling, holding, and distributing articles of food in accordance with this Decree, the

Act, and its implementing regulations; and (2) will be continuously maintained in a sanitary condition;

C. Defendants shall ensure that the Expert retained under paragraph 8(A):

(1) Reviews all FDA inspectional observations of deficiencies at the Sturgis Facility identified in the FDA Form-483 issued on March 18, 2022, and all records related to the detection of *Cronobacter* spp. and/or *Salmonella* spp. in the environment or in-process or finished product at the Sturgis Facility from September 2019 to the present;

(2) Reviews, and modifies as necessary, Defendants' written sanitation procedures including, but not limited to, sanitation standard operating procedures for receiving, manufacturing, processing, preparing, packing, holding, and distributing articles of food ("Sanitation Plan") to verify that the Sanitation Plan complies with the CGMP Regulations for Human Food and the Infant Formula CGMP Regulations and adequately: (a) establishes sanitation controls, monitoring procedures, and corrective actions for: *(i)* manufacturing processes; *(ii)* cleaning (including, but not limited to, cleaning in place), sanitizing, and dry-out operations (including, but not limited to, verified dry-out procedures and validated test methods for dry-out of production equipment and processing environments); and *(iii)* facilities (including, but not limited to, building construction and maintenance to ensure, among other things, adequate water management) and equipment and utensils contained therein; (b) addresses the risks of microbiological contamination from contaminants including, but not limited to, pathogens such as *Cronobacter sakazakii* and *Salmonella* spp.; and (c) protects against the contamination of food and food-contact surfaces and prevents insanitary conditions at the Sturgis Facility;

(3) Reviews, and modifies as necessary, Defendants' written environmental monitoring and testing program ("Environmental Monitoring Plan") to verify that the Environmental Monitoring Plan complies with the requirements in paragraph 11(G);

(4) Reviews, and modifies as necessary, Defendants' written product sampling and testing program ("Product Monitoring Plan") to verify that the Product Monitoring Plan complies with the requirements in paragraph 11(H);

(5) Reviews, and modifies as necessary, Defendants' written employee training program ("Employee Training Program") (in English and any other language necessary to effectively convey the substance of the training) that addresses: (a) maintaining sanitation, conducting adequate sampling and analysis, avoiding bacterial contamination, and controlling pathogens; and (b) the CGMP Regulations for Human Food and the Infant Formula CGMP Regulations, and the requirements in the Sanitation Plan, the Environmental Monitoring Plan, and the Product Monitoring Plan. The Employee Training Program shall include training for new employees and ongoing training programs for existing employees;

(6) Conducts a comprehensive inspection at the Sturgis Facility (including, but not limited to, buildings and equipment and utensils contained therein) and the methods, processes, and controls used to manufacture, process, prepare, pack, label, hold, and distribute articles of food, and certifies in writing to FDA that:

(a) He or she has evaluated the results of environmental monitoring tests, and inspected the Sturgis Facility (including, but not limited to, buildings and equipment and utensils contained therein) and the methods, processes, and controls used to manufacture, process, prepare, pack, label, hold, and distribute articles of food;

(b) Defendants have corrected all deficiencies at the Sturgis Facility identified in the FDA Form-483 issued on March 18, 2022, and any deficiencies identified during the Expert's record review of the detection of *Cronobacter* spp. and/or *Salmonella* spp. in the environment or in any article of food at the Sturgis Facility (including samples collected during production under Specialty Operations), from September 2019 to the present, specifying each deficiency and Defendants' corrections thereof. Where applicable, the Expert may refer to any completed or ongoing action described in Defendants' Form FDA-483 Response; and

(c) Based on the Expert's review and inspection, Defendants' facilities, methods, processes, and controls (including the Sanitation Plan, the Environmental Monitoring Plan, and the Product Monitoring Plan) are: (*i*) in compliance with this Decree, the Act, and its implementing regulations; and (*ii*) adequate to ensure that Defendants' products are manufactured, processed, prepared, packed, labeled, held, and distributed in compliance with this Decree, the Act, the CGMP Regulations for Human Food, and the Infant Formula CGMP Regulations; and

(7) Prepares and submits in writing to FDA a detailed report of all findings, with supporting documentation, and submits the certification, detailed report, and supporting documentation to Defendants and FDA concurrently, within fifteen days after completing the inspection; and

D. Defendants shall provide to FDA an affidavit of compliance, signed by a person with personal knowledge of the facts, stating the fact and manner of compliance with the provisions of paragraphs 9(A) and 9(B). Defendants shall also submit the Sanitation Plan, the Environmental Monitoring Plan, the Product Monitoring Plan, and the Employee Training

Program certified by the Expert pursuant to this paragraph to FDA for review and concurrence, and receive written notification of concurrence from FDA. Within twenty days after receipt of the Expert-certified plans (the Sanitation Plan, the Environmental Monitoring Plan, the Product Monitoring Plan, and the Employee Training Program), unless FDA determines that a longer time frame is necessary, in which case FDA can give Defendants notice that FDA needs an additional twenty days to complete its review, FDA will review the Expert-certified plans and provide written notification to Defendants either concurring with the plans or explaining the basis for FDA's decision not to concur with any plan(s), including the concerns with Defendants' submission. After addressing all concerns described in FDA's written notification of a decision not to concur, Defendants shall submit a revised plan to FDA for review and concurrence. Within fifteen days after receipt of a revised plan, unless FDA determines that a longer time frame is necessary, in which case FDA can give Defendants notice that FDA needs an additional fifteen days to complete its review, FDA will review the revised plan and provide written notification to Defendants either concurring with the revised plan or explaining the basis for FDA's decision not to concur with the revised plan, including the concerns with Defendants' submission. This process shall be repeated until Defendants receive written notification of concurrence from FDA. In no circumstance shall FDA's silence be construed as a substitute for written notification.

General Provisions

10. Subject to the exception described in this paragraph, within twenty-five days after entry of this Decree, Defendants shall destroy all articles of food that Defendants recalled prior to the date of entry of this Decree ("recalled articles"). Defendants shall give notice to FDA that, under FDA's supervision, Defendants are prepared to destroy the recalled articles and shall

specify the proposed time, place, and method of destruction. Defendants shall not commence, or permit any other person to commence, destruction until they have received written authorization from FDA to commence destruction. In no circumstance shall FDA's silence be construed as a substitute for written notification. Within fifteen days after receiving authorization from FDA to commence destruction, Defendants shall, under FDA supervision, complete destruction in compliance with this provision. Defendants shall not dispose of any recalled article in a manner contrary to the provisions of the Act, any other federal law, any court order, or the laws of any state or Territory, as defined in the Act, in which the recalled articles are disposed. Defendants shall bear the costs of destruction and the costs of FDA's supervision at the rates specified in paragraph 17. To the extent that Defendants are under a separate legal obligation to preserve all or a portion of the recalled products, Defendants shall be permitted to segregate and retain such recalled products for the duration of such preservation obligation.

11. After receiving written concurrence from FDA under paragraph 9(D), Defendants shall continuously and effectively comply with the following requirements:

A. Defendants shall immediately implement and follow the Sanitation Plan, the Environmental Monitoring Plan, and the Product Monitoring Plan approved by FDA under paragraph 9(D) and shall ensure that all powdered products at the Sturgis Facility are produced under conditions and practices that comply with these plans and the remaining provisions of this Decree;

B. Prior to distribution of each product lot, Defendants shall ensure that a qualified individual in Defendants' quality unit reviews the batch record, the test results for in-process and finished product, and the environmental monitoring results that pertain to the product lot, and certifies in writing that such lot meets all specifications. Defendants shall

maintain copies of all certifications required by this paragraph at the Sturgis Facility, in a location where the certifications are readily available for reference and inspection by FDA;

C. Within two days after receiving FDA's written notification under paragraph 9(D), Defendants shall assign continuing responsibility for implementing and monitoring the FDA-approved Sanitation, Environmental Monitoring, and Product Monitoring Plans to a person(s) who, by reason of education, training, or experience, is qualified to maintain the Sturgis Facility in a sanitary condition and implement appropriate corrective actions, and Defendants provide such person(s) with the authority and resources to achieve any necessary corrective action. Defendants shall provide to FDA, in writing, the identities, titles, and qualifications of the individual(s) assigned responsibility under this paragraph within ten days after assigning responsibility to such individuals;

D. Within ten days after receiving FDA's written notification under paragraph 9(D), Defendants shall ensure that the FDA-approved Sanitation, Environmental Monitoring, and Product Monitoring Plans are available and accessible (in English and any other language necessary to effectively convey the substance of these documents) to their officers, employees, and all other persons who perform duties at the Sturgis Facility;

E. Within twenty days after receiving FDA's written notification under paragraph 9(D), Defendants shall train their employees, and all other persons who perform duties at the Sturgis Facility, in accordance with the FDA-approved Employee Training Program, to ensure that the individuals who receive, manufacture, process, prepare, pack, label, hold, or distribute articles of food are qualified to perform their assigned duties. Defendants shall submit documentation to FDA demonstrating that they have adequately trained all persons who perform duties at the Sturgis Facility in accordance with the Employee Training Program;

F. Defendants shall provide training to each new employee within five days after the new employee commences duties at the Sturgis Facility, and provide ongoing training programs for existing employees, in accordance with the FDA-approved Employee Training Program;

G. Defendants shall conduct environmental monitoring and testing in accordance with the Environmental Monitoring Plan to demonstrate that the Sanitation Plan is consistently followed to provide systematic control over pathogens, including *Cronobacter* spp. and *Salmonella* spp., to prevent contamination of finished products. Defendants' Environmental Monitoring Plan shall conform to the following requirements:

(1) Environmental monitoring shall include, but not be limited to: (a) collecting samples from equipment and production areas that may pose a high risk of contamination; other environmental sites where food is received, manufactured, processed, prepared, packed, labeled, held, or distributed; and additional areas that may be reservoirs for cross-contamination; (b) analyzing samples in an industry-recognized method that is acceptable to FDA; (c) implementing remedial action, should any pathogen be detected in the environment, including, but not limited to, intensified sanitation measures, intensified sampling and testing measures, comprehensive investigations, and a contamination-source determination (i.e., a root-cause analysis); and (d) conducting trend analyses by a qualified analyst and reviewed by a qualified manager;

(2) A majority of swabs shall be collected from Zone 2 areas (i.e., areas in the vicinity of food contact surfaces) during both routine environmental monitoring and, when appropriate, investigative environmental monitoring. When the Sanitation Plan and/or Environmental Monitoring Plan requires or recommends equipment tear-down, Defendants shall

ensure that swabs are collected from Zone 1 (i.e., food-contact surfaces): (a) after such equipment is disassembled, before being cleaned and sanitized; and (b) after the equipment is cleaned and sanitized. Defendants shall also ensure that, if any *Cronobacter* spp. or *Salmonella* spp. is detected in a Zone 3 environment (i.e., areas surrounding Zone 2 areas), additional swabs are collected from surrounding Zone 2 areas;

(3) If any *Cronobacter* spp. is detected in the environment, Defendants shall speciate each *Cronobacter* spp. isolate to determine whether it is *Cronobacter sakazakii*, and forward each *Cronobacter sakazakii*-positive test result to FDA within twenty-four hours of receipt by Defendants; and

(4) Defendants shall retain each *Cronobacter sakazakii* and *Salmonella* spp. isolate under appropriate storage conditions for three years from the date of the test result detecting the presence of *Cronobacter sakazakii* and/or *Salmonella* spp. in that isolate, and each isolate is to be provided to FDA within five days of receipt of written request;

H. Defendants shall conduct product monitoring and testing in accordance with the Product Monitoring Plan, to ensure that controls are adequate to prevent contamination by pathogens, including *Cronobacter* spp. and *Salmonella* spp. Defendants' Product Monitoring Plan shall conform to the following requirements:

(1) At a minimum, Defendants shall test representative samples from the beginning, middle, and end (i.e., three separate sampling periods) of each lot of each batch of finished product; and

(2) The Product Monitoring Plan shall include remedial action to be implemented should any *Cronobacter* spp. or *Salmonella* spp. be detected in any article of food (including raw ingredients and in-process and finished product batches). As part of the Product

Monitoring Plan's remedial action, if any test of in-process or finished product detects the presence of *Cronobacter* spp. and/or *Salmonella* spp., Defendants shall:

(a) Cease production at the earliest time practicable and, in any event, no later than the completion of any batch then in progress, dispose of the affected in-process and/or finished product batch, conduct a thorough contamination-source determination (i.e., root-cause analysis), adequately remediate the processing equipment and environment, and conduct intensified sanitation measures and intensified sampling and testing measures. Defendants shall maintain records of all these steps and shall make those records available to FDA immediately upon request. After a cessation of production pursuant to this paragraph, Defendants shall not resume production unless and until they receive written notice from FDA that Defendants may resume production. Within fifteen days after receipt of Defendants' written request to resume production, unless FDA determines that, based on the complexity of the issues, a longer time frame is necessary, in which case FDA can give Defendants notice that FDA needs an additional fifteen days to complete its review, FDA will review Defendants' request to resume production and provide written notification to Defendants either permitting resumption or explaining the basis for FDA's decision not to permit resumption of production, including the concerns with Defendants' submission. After addressing all concerns described in FDA's written notification of a decision not to permit resumption, Defendants may submit a new request to resume production, and the process described in paragraph 11(H)(2)(a) shall be repeated until Defendants receive written notification from FDA that they may resume production. In no circumstance shall FDA's silence be construed as a substitute for written notification;

(b) Forward the test results detecting the presence of *Cronobacter* spp. and/or *Salmonella* spp. in in-process and/or finished product to FDA within

twenty-four hours after receipt by Defendants (along with a written statement confirming that Defendants have ceased production in accordance with paragraph 11(H)(2)(a)), speciate each *Cronobacter* spp. isolate to determine whether it is *Cronobacter sakazakii*, and forward each *Cronobacter sakazakii*-positive test result to FDA within twenty-four hours of receipt by Defendants; and

(c) Retain each *Cronobacter sakazakii* and *Salmonella* spp. isolate under appropriate storage conditions for three years from the date of the test result detecting the presence of *Cronobacter sakazakii* and/or Salmonella spp. in that isolate, and each isolate is to be provided to FDA within five days of receipt of written request;

I. Defendants shall prepare a plan that assesses the need for any repair of buildings (such as roofs) and/or equipment (such as spray dryers), including a determination whether to continue repairing or replace that equipment. Defendants shall submit the plan to FDA within four months after receiving written notification from FDA under paragraph 9(D). If applicable, Defendants may refer to any completed or ongoing action described in Defendants' Form FDA-483 Response;

J. In the event that Defendants decide to transfer any of their equipment that is used for production of powdered products from the Sturgis Facility to any other manufacturing site, Defendants shall notify FDA in writing at least forty-five days prior to the planned transfer. Defendants' notification shall include, but not be limited to, a plan for cleaning and sanitizing, and refurbishing if necessary, the equipment, followed by environmental testing for pathogens, prior to the transfer of equipment to any other manufacturing site. Defendants shall not transfer any such equipment unless and until they: (a) receive written concurrence from FDA on the plan to clean, sanitize, and refurbish the equipment; (b) clean, sanitize, and refurbish the equipment in

accordance with the FDA-concurred plan; (c) submit to FDA a detailed written report, with supporting documentation, describing the actions taken to comply with paragraph 11(J); and (d) receive written notification from FDA that Defendants appear to be in compliance with paragraph 11(J);

K. Defendants shall retain an independent person or persons (the "Auditor") who shall meet the criteria for and may be the same person as the Expert described in paragraph 8(A), to conduct audit inspections at the Sturgis Facility of the facilities, methods, processes, and controls used to receive, prepare, process, pack, label, hold, or distribute articles of food. Defendants shall notify FDA in writing of the identity and qualifications of the Auditor within two days after retaining the Auditor. Defendants shall ensure that the audit inspections are conducted as follows:

(1) Defendants shall ensure that, within six months after Defendants resume operations after receiving FDA's written notification pursuant to paragraph 9(D), the Auditor shall conduct an audit at the Sturgis Facility of the facilities, methods, processes, and controls used to receive, manufacture, process, prepare, pack, label, hold, and distribute articles of food to determine whether Defendants are operating in compliance with this Decree, the Act, and its implementing regulations, and to identify any deviations from such requirements. Defendants shall also ensure that the Auditor submits an Audit Report documenting all findings to Defendants and FDA concurrently, within seven days after completing the audit;

(2) Thereafter, Defendants shall ensure that the Auditor conducts audits no less frequently than once every six months for a period of one year, and then annually for the next three years, unless FDA informs Defendants in writing that more frequent audit

inspections and reporting are required. If any Audit Report identifies any deviation from this Decree, the Act, or its implementing regulations, FDA may require the audit cycle be extended;

(3) Defendants shall ensure that, as part of every Audit Report (except the first one), the Auditor assesses the adequacy of actions taken by Defendants to correct all previous audit observations, if any, indicating that Defendants are not in compliance with this Decree, the Act, or its implementing regulations. If the Audit Report contains any audit observations indicating that Defendants are not in compliance with this Decree, the Act, or its implementing regulations, Defendants shall make all necessary corrections within ten days after receipt of the Audit Report, unless FDA notifies Defendants in writing that a shorter time period is necessary or, upon written request by Defendants and/or based on the nature of the correction to be made, that a longer time period is permitted; and

(4) Defendants shall ensure that, within twenty days after the required completion date for any corrective action under this paragraph, the Auditor reviews each and all corrective action(s) taken by Defendants and reports in writing to FDA whether each deviation listed in the Audit Report has been corrected;

L. In the event that the Expert or the Auditor determines that the Sanitation Plan, the Environmental Monitoring Plan, the Product Monitoring Plan, or the Employee Training Program needs to be revised, Defendants shall:

(1) Ensure that the Expert or Auditor reviews the proposed changes and certifies in writing that the proposed changes establish methods, processes, and controls at the Sturgis Facility that are adequate to ensure that articles of food are manufactured, processed, prepared, packed, labeled, held, and distributed in compliance with this Decree, the Act, and implementing regulations ("paragraph L certification");

(2) Ensure that the Expert's or Auditor's paragraph L certification with supporting documentation is submitted to Defendants and FDA concurrently, within five days after completing the review; and

(3) Provide to FDA the revised Sanitation Plan, the Environmental Monitoring Plan, the Product Monitoring Plan, and/or the Employee Training Program, within twenty-four hours of the submission to FDA of the Expert's or Auditor's paragraph L certification. Any change to the Sanitation Plan, the Environmental Monitoring Plan, and/or the Product Monitoring Plan shall ensure that pathogens, including *Cronobacter* spp. and *Salmonella* spp., are systematically controlled to prevent contamination of finished products; and

M. In the event that Defendants terminate their agreement with:

(1) The Expert retained pursuant to paragraph 8(A), Defendants shall notify FDA within five days after such termination and immediately retain another expert who meets the qualifications of the Expert described in paragraph 8(A). Defendants shall notify FDA in writing of the identity and qualifications of the new Expert within five days after retaining the new Expert; and

(2) The Auditor retained pursuant to paragraph 11(K), Defendants shall notify FDA within five days after such termination and immediately retain another expert who meets the qualifications of the Auditor described in paragraph 11(K). Defendants shall notify FDA in writing of the identity and qualifications of the new Auditor within five days after retaining the new Auditor.

12. Defendants and all Associated Persons who have received actual notice of this Decree are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any act at or from the Sturgis Facility that:

A. Violates 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4);

B. Violates 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce articles of food, namely infant formula as defined in 21 U.S.C. § 321(z), that are adulterated within the meaning of 21 U.S.C. § 350a(a)(3);

C. Violates 21 U.S.C. § 331(k) by causing articles of food that are held for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4);

D. Violates 21 U.S.C. § 331(k) by causing articles of food, namely infant formula as defined in 21 U.S.C. § 321(z), that are held for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 350a(a)(3); and/or

E. Results in the failure to implement and continuously maintain the requirements of this Decree, the Act, and its implementing regulations.

13. If, at any time after this entry of this Decree, FDA determines, based on the results of an inspection, the analysis of a sample, report or data prepared or submitted by Defendants, the Expert(s), or the Auditor, or any other information, that Defendants have failed to comply with any provision of this Decree, violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective action,

including, but not limited to, ordering Defendants to immediately take one or more of the following actions, which remedies shall be separate and apart from, and in addition to, any other remedy available to the United States under this Decree or under the law:

A. Cease manufacturing, processing, preparing, packing, labeling, holding, and/or distributing any and all powdered products;

B. Recall, at Defendants' expense, any and all articles of food that have been distributed or are under the custody and control of Defendants' agents, distributors, customers, or consumers that, in FDA's judgment, are adulterated or otherwise in violation of this Decree, the Act, or its implementing regulations. Defendants shall initiate the recall(s) within twenty-four hours after receiving notice from FDA that a recall is necessary;

C. Destroy, under FDA supervision, all articles of food (including raw ingredients and in-process and finished products) that are in Defendants' possession, custody, or control. Defendants shall bear the costs of destruction and the costs of FDA's supervision at the rates specified in paragraph 18. Defendants shall be responsible for ensuring that the destruction is carried out in a manner that complies with all applicable federal and state environmental laws, and any other applicable federal or state law. To the extent that Defendants are under a separate legal obligation to preserve all or a portion of such articles of food, Defendants shall be permitted to segregate and retain such articles of food for the duration of such preservation obligation;

D. Revise, modify, expand, or continue to submit any reports or plans prepared pursuant to this Decree;

E. Submit additional reports or information to FDA as requested;

F. Submit samples to a qualified laboratory for analysis;

G. Institute or re-implement any of the requirements set forth in this Decree;

H. Issue a safety alert; and/or

I. Take any other corrective actions as FDA, in its discretion, deems necessary to protect the public health or bring Defendants into compliance with this Decree, the Act, or its implementing regulations.

Any cessation of operations or other action described in this paragraph shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations. Upon Defendants' written request to resume operations, FDA will determine whether Defendants appear to be in such compliance, and, if so, issue to Defendants a written notification permitting, as appropriate, resumption of operations. Within twenty days after receipt of Defendants' written request to resume production, unless FDA determines that, based on the complexity of the issues, a longer time frame is necessary, in which case FDA can give Defendants notice that FDA needs an additional twenty days to complete its review, FDA will review Defendants' request to resume production and provide written notification to Defendants either permitting resumption or explaining the basis for FDA's decision not to permit resumption of production, including the concerns with Defendants' submission. After addressing all concerns described in FDA's written notification of a decision not to permit resumption, Defendants may submit a new request to resume production, and the process described in paragraph 13(I) shall be repeated until Defendants receive written notification from FDA that they may resume production. In no circumstance shall FDA's silence be construed as a substitute for written notification. The cost of FDA inspections, investigations, supervision, examinations, sampling, testing, travel time, and subsistence expenses to implement and monitor the remedies set forth in this paragraph shall be

borne by Defendants at the rates specified in paragraph 17. This provision shall be separate and apart from, and in addition to, all other remedies available to FDA.

14. If FDA issues a directive pursuant to paragraph 13, the following process and procedures shall apply:

A. Unless a different time frame is specified by FDA in its directive, within ten days after receiving such directive, Defendants shall notify FDA in writing either that: (1) Defendants are undertaking or have undertaken corrective action, in which event Defendants shall also describe the specific action taken or proposed to be taken and the proposed schedule for completing the action; or (2) Defendants do not agree with FDA's directive. If Defendants notify FDA that they do not agree with FDA's directive, Defendants shall explain in writing the basis for their disagreement and, in doing so, may provide specific alternative actions and time frames for achieving FDA's objectives. After receipt of Defendants' notification and explanation, FDA will review Defendants' notification and explanation and, in writing, affirm, modify, or withdraw its directive, as FDA deems appropriate. If FDA affirms or modifies its directive, it will explain the basis for its decision in writing. The written notice of affirmation or modification shall constitute final agency action. If FDA affirms or modifies its directive, Defendants shall, upon receipt of FDA's affirmed or modified directive, immediately implement it, and may, if Defendants so choose, bring the matter before this Court. While seeking Court review, Defendants shall continue to implement and fully comply with FDA's directive, unless and until the Court stays, reverses, or modifies FDA's directive. Any judicial review of FDA's directive under this paragraph shall be made pursuant to paragraph 25; and

B. The process and procedures in paragraph 14(A) shall not apply to any directive issued pursuant to paragraph 13 if such directive states that, in FDA's judgment, the

matter raises a significant public health concern. In such case, Defendants shall, upon receipt of such directive, immediately and fully comply with the terms of that directive, and the directive shall be a final agency decision. Should Defendants seek to challenge any such directive, they may petition the Court for relief while they implement FDA's directive. Any judicial review of FDA's directive under this paragraph shall be made pursuant to paragraph 25.

15. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect the Sturgis Facility, collect samples, and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and implementing regulations. During such inspections, FDA representatives shall be permitted to: have immediate access to the Sturgis Facility and/or other place(s) of business including, but not limited to, all buildings or other structures, equipment, raw ingredients, in-process materials, unfinished and finished materials and products, containers, and labeling; take photographs and make video recordings; take samples, without charge to FDA, of raw ingredients, in-process materials, unfinished and finished materials and products, containers, and labeling; and examine and copy all records relating to the receipt, holding, and distribution of any and all articles of food and their components. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate and apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

16. Defendants shall promptly provide any information or records to FDA upon request regarding the receipt, manufacture, processing, preparing, packing, labeling, holding, and/or distributing of articles of food. Defendants shall maintain copies of the Sanitation Plan, the Environmental Monitoring Plan, the Product Monitoring Plan, and the Employee Training

Program, along with copies of all records required by such plans and this Decree, at the Sturgis Facility, in a location where the records are readily available for reference and inspection by FDA. Defendants shall retain all records referred to in this paragraph for at least three years after the date the records are prepared.

17. Defendants shall pay all costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with this Decree, including all transportation and associated costs for FDA investigators and experts, at the standard rates prevailing at the time the costs are incurred. As of the date of entry of this Decree, these rates are: $105.46 per hour or fraction thereof per representative for inspection and investigative work; $126.24 per hour or fraction thereof per representative for analytical or review work; $0.59 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate for subsistence expenses where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

18. Within five days after the entry of this Decree, Defendants shall post a copy of this Decree in a common area at the Sturgis Facility, and publish the Decree on an internal website and a publicly-available website maintained and/or controlled by Defendants. Defendants shall ensure that this Decree remains posted as described herein for as long as this Decree remains in effect. Within ten days after entry of this Decree, Defendants shall provide to FDA an affidavit of compliance, signed by a person with personal knowledge of the facts, stating the fact and manner of compliance with the provisions of this paragraph.

19. Within ten days after the entry of this Decree, Defendants shall provide a copy of this Decree by electronic mail to each and all Associated Persons. Within twenty days after the date of entry of this Decree, Defendants shall provide to FDA an affidavit of compliance, signed by a person with personal knowledge of the facts, stating the fact and manner of compliance with the provisions of this paragraph and identifying the names, addresses, and positions of all persons who have received a copy of this Decree pursuant to this paragraph. Within seven days after receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

20. Within fifteen days after entry of this Decree, Defendants shall hold a general meeting or series of smaller meetings for all Associated Persons, at which they shall describe the terms and obligations of this Decree. Within twenty days after entry of this Decree, Defendants shall provide to FDA an affidavit of compliance, signed by a person with personal knowledge of the facts, stating the fact and manner of compliance with the provisions of this paragraph and a copy of the agenda, list of attendees, and meeting minutes from the meeting(s) held pursuant to this paragraph.

21. In the event that any Defendant becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants shall immediately provide a copy of this Decree by electronic mail to such Associated Person(s). On a quarterly basis, Defendants shall provide to FDA an affidavit of compliance, signed by a person with personal knowledge of the facts, stating the fact and manner of compliance with the provisions of this paragraph and identifying the names, addresses, and positions of the additional Associated Person(s) who have received a copy of this Decree pursuant to this paragraph. Within seven

days after receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

22. Defendants shall notify FDA in writing at least thirty days before any change in ownership, name, or character of their business at the Sturgis Facility that occurs after entry of this Decree including, but not limited to, any of the following, if they may affect obligations arising out of this Decree: (1) an incorporation, reorganization, relocation, dissolution, bankruptcy, assignment or sale resulting in the emergence of a successor corporation; the creation or dissolution of subsidiaries; the creation of any additional entities that engage in the manufacture and distribution of articles of food; the discontinuation of any line of powdered product; and any other change in the structure or identity of Abbott Nutrition or change in the responsibility of any individual defendant that affects the Sturgis Facility; and (2) the sale or assignment of any business assets, such as buildings, equipment, or inventory. Defendants shall provide a copy of this Decree to any prospective successor or assign at least twenty days before any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten days before any such assignment or change in ownership.

23. If any Defendant fails to comply with any provision of this Decree, the Act, or its implementing regulations, including any time frame imposed by this Decree, then Defendants shall pay to the United States of America thirty thousand dollars ($30,000) in liquidated damages for each day such violation continues. The total amount of such liquidated damages shall not exceed five million dollars ($5,000,000) annually. The remedy in this paragraph shall be in addition to any other remedies available to the United States under this Decree or the law.

24. Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees (including overhead), travel expenses incurred by attorneys and witnesses, investigational and analytical expenses, expert witness fees, administrative and court costs, and any other costs or fees incurred by the United States in bringing such an action.

25. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, to the extent that these decisions are subject to review, shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

26. All notifications, certifications, reports, correspondence, and other communications to FDA required by the terms of this Decree shall be prominently marked "Consent Decree Correspondence," shall reference this civil action by case name and civil action number, and shall be submitted electronically to the Program Division Director, Office of Human and Animal Food Operations, Human and Animal Food Division East 6, at ORAHAFEAST6FIRMRESPONSES@fda.hhs.gov. If electronic submission is not possible, communications shall be addressed to the attention of OHAFO East 6 Program Division Director, FDA, 550 West Jackson Boulevard, Chicago, Illinois 60661.

27. This Decree shall apply only to Defendants and Associated Persons, as defined in paragraph 7(A), involved with the manufacture, processing, preparing, packing, labeling, holding, or distribution of powdered products at or from the Sturgis Facility.

28. No sooner than sixty months after resuming production after receipt of written notification from FDA under paragraph 9(D), Defendants may provide written notice to FDA that they seek relief from this Decree. If, at the time of such notice, in FDA's judgment Defendants have maintained a state of continuous compliance with the terms of this Decree, the Act, and all applicable laws and regulations for at least sixty months after resuming production after receipt of written notification from FDA under paragraph 9(D), the Defendants may petition the Court to grant such relief and the United States will not oppose Defendants' petition.

29. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

IT IS SO ORDERED, this 16th day of May, 2022.

/s/ Hala Y. Jarbou
HALA Y. JARBOU
UNITED STATES DISTRICT JUDGE

The undersigned hereby consent to the entry of the foregoing Decree.

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